UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/570,835	05/19/2006	Joachim Arzt	06022	8773

24124 7590 10/06/2008

BOHAN MATHERS
PO BOX 17707
PORTLAND, ME 04112-8707

EXAMINER	
UNDERDAHL, THANE E	
ART UNIT	PAPER NUMBER
1651	
MAIL DATE	DELIVERY MODE
10/06/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/570,835	ARZT ET AL.	
	Examiner	Art Unit	
	THANE UNDERDAHL	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *6/17/08*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *5-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/17/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is in response to the Applicant's reply received 6/17/08. Claims 5-11 are pending. No claims are withdrawn. No claims are cancelled. Claims 5 and 11 have been amended. No claims are new.

Response to Applicant's Arguments— 35 U.S.C § 112

In the response submitted by the Applicant both of the 35 U.S.C § 112 first paragraph rejections for enablement and written description of claims 5-11 are withdrawn in light of the Applicant's amendments to claim 5 which include that the organ is "suspended" rather than "floating" and adding the limitation "perfusate through said extracorporeal organ".

In the response submitted by the Applicant both of the 35 U.S.C § 112 second paragraph rejection of claims 5-11 for being indefinite are withdrawn in light of the Applicant's amendments to claim 5 which clarify the components of the VSP (vitality-preserving fluid) as clearly a dialysate and a perfusate while clearly defining their functions in the apparatus.

Response to Applicant's Arguments— 35 U.S.C § 102

In the response submitted by the Applicant the 35 U.S.C § 102 (b) rejection of claims 5, 6 and 11 based on Brasile is withdrawn in light of Applicant's amendments to claim 5 that was previously mentioned.

Response to Applicant's Arguments— 35 U.S.C § 103

In the response submitted by the Applicant the 35 U.S.C § 103 (a) rejections of claims 5-9 and 11 over Brasile and claims 5-11 over Brasile in view of Bacchi et al. are withdrawn in light of Applicant's amendments.

Objection to the Amendments to the Specification

The Examiner objects to the amendments of the specification. These amendments rely on support from the untranslated claims of the German PCT of this application. The Examiner is not certified to translate German and as such cannot verify the support cited for these amendments. This objection can be overcome by providing a certified translation of the claims of the German PCT.

New Rejections Necessitated by Amendment

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5-11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Applicant cites support for the new amendments to claim 5 and 11 in the claims of the originally filed PCT which is in

German. The Examiner only received an English translation of the specification of the PCT and not the claims on 3/3/06. Therefore since the Examiner is not certified to make translations in German the support cited in the PCT cannot be verified and as such the new claim amendments are new matter. This rejection can be overcome by providing a certified translation of the claims of the German PCT.

Claim Rejections - 35 USC § 103

Claims 5-9 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brasile with the support of Cooksley (U.S. Patent # 3968346)in view of Kaplan et al. (J. Nuclear Medicine, 1965) or alternatively Dhondt et al. (Kidney International, April 2003).

These claims are to a storage system for an extracorporeal organ comprising the following:

a) An organ perfusion chamber having a wall with connections to the extracorporeal organ and also contains a reservoir of stored fluid
b) A protective cover inside the perfusion chamber which encloses the organ and provides a complete barrier between the organ and the stored fluid
c) A vitality-preserving fluid circuit (**VPF-Circuit**) that comprises the following
    - Perfusate circulation system (**PCS**) that circulates a perfusate through the extracorporeal organ
    - Dialysate circulation system (**DCS**) that circulates a dialysate that dialyses the perfusate of the PCS

d) The stored fluid in the reservoir is the dialysate for the DCS

e) The protective cover encloses the extracorporeal organ within the space defined by protective cover and a portion of the wall of the organ profusion chamber with said connectors.

f) The organ inside said protective cover is maintained in a suspended state inside protective cover and except for the portion of the organ with said wall and connectors, is completely surrounded by said storage fluid.

This system further comprises a temperature control device for controlling the temperature of the dialysate such as a heating mat. This temperature control device has temperature control loops and is integrated into the wall of the system. The protective cover is an impermeable plastic bag.

The Examiner notes several points when interpreting these claims. Applicant's response did clarify that Figure 1 of the specification is a top plane view and not a side elevation view. However this picture and the description in the specification of "the organ is maintained in a suspended state inside said protective cover and except for said portion of said wall with said connectors is completely surrounded by said storage fluid" (see claim 5) does not limit that the phrase to mean that the organ is suspended and completely submersed in the storage fluid. Indeed a common analogy would be a ship on the ocean, where it is suspended on the water and is completely surrounded by the water but is not completely submersed in the water. Therefore the term "completely surrounded by said storage fluid" does not limit that the storage fluid surrounds the entire three dimensions of the organ but can also read on an organ this is surrounded in

at least two dimensions. The top plane view of the picture does not provide support for a submerged organ since looking down at the organ of this two dimensional view you indeed see that the organ is surrounded by fluid but without the third dimension you do not know if it is surrounded in all three dimensions, thus being submersed in the fluid.

Also the phrase in claim 5 "wherein said organ is maintained in a suspended state" does not limit how the organ is maintained in the suspended state. While the Applicant may believe the claim is limited to the organ being suspended by floating on the storage fluid, there are no limitations in the claim that support that belief. Therefore art reading on any method of suspension will read on the invention. The Applicant provides exhaustive discussion on the importance of the density of the storage fluid in suspending or floating the organ. The Applicant even refers to this characteristic as an advantage of the system (Applicant's response, pg 12, paragraph 15). Nevertheless there are no limitations in the claims that reflect the importance of this discussion so for the time being such arguments are not commensurate with the scope of the claims and cannot be given patentable weight.

Now considering the prior art. Brasile teach an organ perfusion chamber that surrounds the organ in a protective cover in a space defined by a wall with connectors (Brasile, Figure 3 and Figure 4, #36). This protective cover #36 can be a sac or a pouch filled with gas, fluid or gel (Brasile paragraph 14 and 67) or “a mesh like fabric that suspends the organ in a sling like fashion” (Brasile, paragraph 67). Brasile teaches that this protective cover #36 suspends the organ in a sling like fashion over the perfusate reservoir (#38) and also prevents the surface of the organ from contacting the

perfusate stored in the reservoir (Brasile, Figure 1). This perfusate reservoir can contain the various components of a warm perfusion system (Brasile, paragraph 71) such as heaters and sensors (Brasile, paragraph 31). The perfusate is send to a dialysis unit (#50) for recycling (Brasile, Figure 1). Brasile also teaches that this perfusion reservoir can be separated from the organ chamber (Brasile, paragraph 69). While Brasile does not teach that the dialysate reservoir is not under the organ this would be obvious in view of the teachings of Kaplan et al. or alternatively Dhondt et al.

Both Kaplan et al. and Dhondt et al. teach that their dialysis systems require substantial reservoirs for their dialysate (Dhondt, Figure 1 and Kaplan, Figure 5). One of ordinary skill in the art would recognize that the dialysis system of Brasile would also require a reservoir for their dialysate. One of ordinary skill in the art would recognize that simply switching the positions of one fluid reservoir in the invention of Brasile et al. for another would be obvious. Brasile teaches that the organ can be supported in a sling like fashion over the perfusate fluid reservoir via a sac that isolates the organ form perfusate (Brasile, paragraph 66). Brasile teaches that this perfusate reservoir can be separated from the organ chamber (Brasile, paragraph 69). It would be obvious to one of ordinary skill in the art that another liquid reservoir could be put in place of the perfusate reservoir so the organ can still be supported in a sling like fashion over the liquid. Since the organ has no external contact with the reservoir because of the protective sac, the type of liquid it was slung-over would be obvious since any other aqueous liquid would appear to have similar characteristics and interactions with the organ though the membrane. Unless evidence of criticality is provided that either the

perfusate liquid or the dialysate liquid would have advantageous characteristics or interactions with the organ through the membrane, switching the position perfusate reservoir with the dialysate reservoir would be obvious, since both are aqueous liquids and have similar physical characteristics.

The above references do not specifically teach a temperature control device integrated into the wall of the organ perfusion chamber. However based on the disclosure by Brasile it would be prima facia obvious at the time of filing to modify the invention to integrate the temperature control device into the wall, since Brasile already places the temperature control sensors of the device in the perfusion chamber. Furthermore M.P.E.P. § 2144.04 B state that making a device integral "would be merely a matter of obvious engineering choice" and as such is prima facie obvious to make the temperature control device integral with the perfusion chamber.

Also since Brasile teach that the temperature controller maintains the temperature between 25-37 ^{o}C based on the input it receives from the sensor (page 7, paragraph 60) it is obvious that one of ordinary skill in the art would recognize that the system contains temperature control feedback loops.

Claim 7 limits the temperature control device to a heating mat.

Brasile teach an organ perfusion chamber with a heat exchanger and a temperature sensor situated within the organ perfusion chamber (page 7, paragraph 60). Brasile does not teach that the heat exchanger is a heating mat. However it would have been obvious to someone skilled in the art at the time the invention was made that multiple methods can be used to heat the storage solution included a water heater to

circulate warmed water around the reservoir (page 7, paragraph 60). One of ordinary skill in the art would recognize that a heat exchanger can include heating elements as well as a heating mat since both are known in the art to heat liquid as taught by Cooksley et al. (col 2, lines 65-70). Therefore it would be *prima facia* obvious to use a heating mat as a heat exchanger for the perfusion chamber. The reference above render obvious claims 5-9 and 11.

Claims 5-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over over Brasile with the support of Cooksley in view of Kaplan et al. or alternatively Dhondt et al. as applied to claims 5-9, and 11 above, and further in view of Bacchi et al. (U. S. Patent # 5,285,657, 1994).

The description and rejection of claims 5-9 and 11 are listed in the 35 U.S.C § 103(a) rejection over Brasile in view of Kaplan et al. or Dhondt et al. Claim 10 further limits that the organ perfusion chamber is hermetically sealed against fluid and pressure.

While Brasile and additional references of Dhondt or Kaplan do teach an organ perfusion chamber in combination with a temperature control device and dialysis system they do not specifically teach that the organ perfusion chamber is hermetically sealed against fluid and pressure. However Brasile does teach that it is important to minimize perfusion contamination due to contact with air (Brasile, page 9 paragraph 78) which provides motivation to hermetically (airtight) seal the chamber. However it would have been obvious to someone skilled in the art at the time the invention was made to make

the organ perfusion chamber hermitically sealed in view of Bacchi et al. who teach an insulated organ perfusion chamber (Bacchi, col 1, lines 45-50) for extracorporeal organ transport (Bacchi, see abstract). Bacchi et al. teach that the lid of this chamber is hermetically sealed (col 7, line 45-50).

It would have been obvious to someone skilled in the art to modify the invention of Brasile with the hermetically sealed lid taught by Bacchi et al. The motivation is provided by Brasile who desires minimal contact with air and the organ. Bacchi et al. provides the reasonable expectation of success by making an organ perfusion chamber that is hermetically sealed.

Furthermore, M.P.E.P. § 2144.06 holds that it is obvious that since both devices are known for the same purpose (extracorporeal organ storage) it would be obvious to combine the elements of both devices to form a third device used for the same purpose. Also Brasile and Bacchi et al. teach similar devices to preserve organs so applying the improvement of Bacchi et al. to the system of Brasile is simply using a known technqiue or characteristic to improve a similar device ((KSR International Co. v. Teleflex Inc., 550 U.S.--, 82 USPQ2d 1385 (2007))

Therefore, the invention as a whole would have been prima facie obvious at the time of filing in view of the references listed above and as such claims 5-11 are not allowable.

In summary no claims, as written, are allowed for this application.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

In response to this office action the applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP § 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 U.S.C. § 102 or 35 U.S.C. § 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is requested to provide a list of all copending U.S. applications that set forth similar subject matter to the present claims. A copy of such copending claims is requested in response to this Office action.

CONTACT INFORMATION

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thane Underdahl whose telephone number is (571)

272-9042. The examiner can normally be reached Monday through Thursday, 8:00 to 17:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached at (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leon B Lankford/
Primary Examiner, Art Unit 1651